My Research, Human Protocols (MRHP)
PI User Guide
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System Requirements

Browsers
MRAP is compatible with Internet Explorer, Firefox, Chrome and Safari. Mobile devices are not supported at this time.

Pop-ups
Pop-ups must be enabled to use the My Research applications. If you are unable to open a page or window, (e.g. creating/opening a document) check that your pop-ups are enabled.

Chrome
In Chrome, the pop-up blocker appears with a red X at the top right of your screen. Click on blocker icon.
Select “Always allow pop-ups from ppm-wd.utoronto.ca”

Internet Explorer
In IE, a pop-up block warning will appear at the bottom of the page.

Click “Options for this site”.

Select “Always allow”. IE will then refresh the screen and take you back to your opening page.

Firefox
In Firefox the pop-up blocker warning will appear at the top left of your screen.

Click on the “Options” button on the right hand side of your screen.

Select “Allow pop-ups from ppm-wd.utoronto.ca”.
Safari

In Safari, there will be **no warning** that pop-ups are being blocked.

**Click on Safari in the browser header and select Preferences from the drop-down menu**

Select the Security tab and un-click “Block pop-up windows”.

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**Help Desk**

Remember, the My Research Help Desk staff is always pleased to assist you if you run into technical problems. The Help Desk is staffed during business hours, Monday to Friday and may be reached at (416) 946-5000 or raise@utoronto.ca.

For questions related to the content of the human protocol, please contact Joshua van Ry, Research Ethics Coordinator, (416) 946-3273 or ethics.review@utoronto.ca
Navigation
Landing Page
The My Research – Human Protocols (MRHP) system is an extension of the existing My Research system and may be accessed from the landing page - http://aws.utoronto.ca/services/my-research-mr/ (please bookmark this page for future reference).

When you click the “Login to My Research” button on the landing page you will be taken to a login page

Logon
1) Enter your UTORid username & password

(Do NOT bookmark the login page – it will only function when you have been passed from the landing page.)
Logout
In order to protect your data from unauthorized intrusion **be sure to click the “Log off” button** when you are finished working on the system. Closing the browser is not sufficient. The **Log off button** only appears on the main page and not on pop-ups.

As an additional security measure, your session will automatically be terminated 4 hours after you initially log in. Unsaved data will be lost.

Welcome Page
When you first log in, the Welcome page will be open. This provides system maintenance/down-time information as well as updates on other issues. The system employs 3 levels of navigation. For MRHP you will utilize two of the tabs in the 1st level navigation; Inbox and My Research.
The Inbox holds all the “tasks” which have been assigned to you. There is one Inbox for all My Research subsystems. Tasks from all the subsystems are consolidated for the user in this Inbox. To help users identify what is required, the Inbox displays a number of data points related to the task:

- **System** – e.g. MRHP
- **Number** – e.g. Protocol Number
- **Task** – e.g. Revise
- **Doc Type** – e.g. Original, Amendment, Renewal, etc.
- **Subject** – e.g. Protocol Title
- **From** – user initiating the process, e.g. the PI
- **Due Date**
- **Sent Date**
- **Other** – for MRHP this is the REB and Risk Level related to the protocol
- **Status** – New or In Progress

Users may sort the Inbox on any one of the columns by clicking on the column header. To change the order of the sort click again.

To access the task click on the Subject.

Once a task is completed it will disappear from the user’s Inbox when the Inbox refreshes. You may manually trigger a refresh by clicking on the refresh icon.
Principal Investigators – Human Participant Protocols

Submit a Protocol

The role of Principal Investigator may be assigned to the following types of users:

- Faculty Members (research & teaching stream)
- External Applicants
- Undergraduate & Graduate
- Post-doctoral Fellows

Faculty member roles will be automatically assigned based on the user’s Human Resources record. External applicants will be assigned manually upon request from the Office of Research Ethics. Student and Post-doctoral Fellows will be assigned by the relevant supervisor.

PI’s List of Protocols

To see a list of your existing protocols or to submit a new protocol, click through the following path:

1. My Research
2. Human Research Protocols
3. My Human Research Protocols

The list is parsed under two tabs; Protocol Search for PI – Submitted (x) and Protocol Search for PI – Unsubmitted (x).

The Submitted tab links to the Folder View (details below) and the Unsubmitted tab gives you a list of protocol documents which have been created but not submitted. (x) equals the number of documents contained under the tab.

When a protocol is selected, some basic information is displayed in the Protocol Header Information section of the screen.

New Original Applications

To submit a new protocol click on the “Create New Protocol” action button.

There are three main types of protocols which may be submitted for review at the University:

- Investigator Submission
- Course Template
- TAHSN Approved Protocol
Not all protocol types will be available to all users, your role at the University determines which protocol types are available for your use.

**Investigator Submission** is available for all users who have a research role at the University.

**Course Template** is only available to users who may teach a course at the University.

**TAHSN Approved Protocol** is only available to users who may hold a protocol at one of the fully affiliated teaching hospitals.

<table>
<thead>
<tr>
<th>Protocol Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Protocol Type" /></td>
</tr>
</tbody>
</table>

**Investigator Submission**
This form is common to all users who have received the Principal Investigator role.

**Course Template**
If you are an undergraduate or graduate course instructor with an assignment that involves human participants, select the Course Template. Several departments and faculties have established their own Delegated Ethics Review Committees (DERCs) to review Course Template protocols. **Do not submit a Course Template through MRHP if the protocol is minimal risk and your unit has a DERC.** Course-based research reviewed through a DERC must be minimal risk. In exceptional circumstances if a unit supports higher risk course-based research, protocols must be submitted for ethics review through MRHP.

**TAHSN Protocols**
Choose TAHSN hospital-based human research where the University is involved in a peripheral capacity: *administration of funds, graduate student involvement* and/or *analysis or storage of personal data or biological samples*. Under these circumstances select “Submit a TAHSN approved research protocol”. This form gathers some basic administrative information and will prompt you to upload a copy of the TAHSN protocol approval letter.
University of Toronto Human Protocol Form

Help in completing the contents of the form

The “Protocol Form Instructions” on the sidebar opens a help page on the Vice President Research and Innovation website that provides information on the entire form. The “Page Help” will take you directly to that section of the larger help document which is relevant to the current page.

Navigating from one page to the next will save the contents entered on the page.

Fields marked with a red asterisk (*) are mandatory.

Validation, Submission and Error Messages

You may validate your protocol for mandatory data as you work through the protocol form by clicking the Validate button. If the Validate button is not visible on your page navigate to the Undertaking page and click on the Validate button. This will validate the entire protocol and will activate the Validate button on all pages of the protocol.

To submit the application you must confirm your acceptance of the terms of the Undertaking. When you subsequently click Submit on the Undertaking page, the system will automatically perform a validation check for completion of all mandatory fields.
In the event that validation fails on submission or when manually invoked, the sections with errors will be flagged with a red exclamation point “!” in the side menu. When you navigate to the marked page a detailed error message will be displayed.

Saving an incomplete protocol document
At any point in the process you may save the form and return to it at a later date. Unsubmitted documents will be found under the Protocol Search for PI – Unsubmitted (x) tab. You may also forward an application to a PI Assistant (PIA) for action. Details on set-up of PIAs are found below.

Amendments
Amendments utilize the same user interface as the Original Protocol submission process. Select the protocol for which you would like to submit an amendment by clicking on the protocol in the list of your submitted protocols. Then click on the Create Amendment button. Only approved protocols may be amended (hint - the protocol will have an expiry date). If you have an unsubmitted amendment the system will not allow you to create another amendment document. The unsubmitted amendment to the protocol will be found under the “Unsubmitted” tab.

On the first screen of an amendment you will be asked to briefly describe the proposed amendment or modifications. The relevant sections of the protocol should then be amended.

Amendments are based on the currently approved version of the protocol.

Renewals
Select the protocol for which you would like to submit a renewal by clicking on the selection button on the left had side of the list of your submitted protocols. Then click on the Create Renewal button. Only approved protocols may be renewed (hint - the protocol will have an expiry date). If you have started a renewal for a protocol but have not submitted it, the Create Renewal button will not be activated when you select the protocol. The unsubmitted renewal to the protocol will be found under the “Unsubmitted” tab.

Renewals utilize the same interface as the original protocol and are built on the currently approved version of the protocol, e.g. if you submitted an original protocol and subsequently amended the protocol the renewal would be based on the amended version of the complete protocol. As a result most fields will already be populated. The History – Progress section, where you outline the progress in the most recent year, will require completion before the renewal can be submitted.

If desired, you may amend your protocol at the same time you submit your renewal.

Protocols may be renewed on an annual basis, to a maximum of six renewals.

Revisions
Original protocol submissions, amendments and renewals may be returned to you for revision prior to approval. If a protocol document has been returned to you for revision you will receive an email notification. The returned document will be found in your My Research Inbox. Open the protocol by clicking on the link in the Inbox. Once, opened, there are two options to view the comments on the document. The “Reviewer Comments” link in the upper right hand corner of the screen will display any comments associated with that particular screen. Alternatively, on the left hand side of the screen you will see an additional section labelled “Reviewer Comments”. This link will open all the comments associated with the document. On this page you will also see the REB’s recommendation, e.g. Revise – Return to ORE for Review & Approval. You do not need do anything to direct the revised document. When you submit the revised document, the system will automatically direct it to the specified office for review. Revisions, like new documents, are submitted via the Undertaking page.

Other Document Types
To create an Adverse Events Report (AER), a Protocol Deviation Report (PDR) or a Protocol Completion report (PCR), select the relevant protocol from your list of protocols and click the corresponding action button. As with Amendments and Renewals, the protocol must be approved prior to the creation of an AER, PDR or PCR. If the protocol has not been approved these buttons will not be activated. You may submit multiple AERs and PDRs for a protocol but only one PCR.
Protocol Deviation Report

A protocol deviation is any departure from the REB-approved ethics review application form that has occurred without prior approval from the REB (e.g., changes to the study procedures, consent process, data protection measures). The submission of this form does not necessarily indicate wrong-doing; however follow-up procedures may be required.

To create the Protocol Deviation Report, select the relevant protocol and click the Create PDR button.

Adverse Events Report

Researchers must report adverse or unanticipated events that occur to participants in the course of the research process. To create an Adverse Events Report, select the relevant protocol and click on the Create AER button.

Reporting to the ORE should be done as soon as possible.

Protocol Completion Report

The Protocol Completion Report (PCR) is required when research using the protocol has been completed. For ongoing research, a PCR on the protocol will be required after 7 years, (Original and 6 Renewals). A continuation of work beyond 7 years will require the creation of a new protocol.

To create the PCR, select the relevant protocol and click the Create PCR button.

Legacy Protocols

Legacy Protocols are those protocols that were active at the time of MRHP implementation. These protocols have been imported into MRHP. Amendments, Renewals, PDRs, AERs, and PCRs for these protocols need to be completed through MRHP. When completing these documents for a legacy protocol you will notice that most of the fields will not be completed as only limited information was available for importation. You are not required to fill out every empty field when submitting an Amendment or Renewal of a legacy protocol as the content validation for these protocols has been modified. Validation checks will verify completion of the Amendment section when submitting an Amendment and the History – Progress section when submitting a Renewal. Please upload a copy of the currently approved copy of your protocol when submitting a either an Amendment or Renewal of a legacy protocol.

Copy Function

The copy function allows you to copy the contents of a protocol. If the protocol has been approved it will copy the most recently approved version of the protocol. Due to the fact that only minimal system information was available for importation, the copy function has been disabled for legacy protocols.

NB: Do not use the copy function to create a Renewal as this will create a new protocol number.
In addition to the functionality described above, the Original, Amendment and Renewal user interfaces share functionality for Notes, Status History, Change History, Generate PDF, and Protocol Form Instructions.

The Protocol Form Instructions link will take you to the top of the instruction page. The Page Help links referenced above are anchored to the page specific sections of the help document.

The Generate PDF link will create a PDF of the current document which may be saved locally.

Notes
Notes may be created and read by any user who has access to the protocol, e.g. a PI, a PIA, an REB member. There are two types of Notes; system generated notes and user created notes. System generated notes are the notifications which are generated by MRHP when a task has been assigned to a user. User created notes are, as the title implies, created by MRHP users.

The number in the bracket is a counter for the number of user generated notes for the protocol.

To create or view existing notes click on the Notes link in the side navigation panel. A pop-up window will be generated which will allow you to search and view existing notes or create new notes. Click on New Note to create a new user generated note.

A new pop-up window will open to allow you to enter a subject line and the note text. Both fields are mandatory. You may then simply create the note, (click Create Note), or send a notification to another user that a note has been created, (click Create & Notify).
If you choose to notify another user that the note has been created, a search box will pop-up. As it is likely that many of the notes will be directed toward the PI, a feature has been added to allow the user to simply tick the box to notify the PI. When you click the Send button the user will get an email notification that a note has been added to the protocol. To encourage capture of any protocol related correspondence within the MRHP system, the recipient must login to the My Research system to see the note contents.

**Status History**

The Status History link generates a report in a pop-up window. This report allows users to trace the history and current state of the protocol review process, e.g. Under Delegated Review. All statuses are tracked by date and time. Where a document has been returned for Revision a new version number will be displayed in the left hand column.

**Change History**
The Change History generates a report which outlines the changes made between the current version of the protocol and the previous version of the protocol. If an original protocol application is sent back for revision, the change report will display the differences between the current version of the protocol and the previous version of the protocol.

The report may be accessed from the side menu in the protocol user interface.

You may look at the entire document or you may focus on those sections that have been changed. When a new amendment (or renewal) is created, the change report will compare the new document with the currently approved version of the protocol. In the example below a new renewal is being developed. The current document is on the left-hand side of the screen.

Folder View

The Folder View provides access to all documents associated with a protocol; any Currently Approved version of the protocol, the Original application and any Amendments, Renewals, Adverse Events Reports, Protocol Deviation Reports, Protocol Completion Report and, in future, Post Approval Review documents.
To access the Folder View click on the My Human Research Protocols link to see a list of your submitted protocols, select the Human Protocol Search for PI – Submitted tab and then either click on the relevant Protocol Title or select the protocol and click the Open Folder View action button.

The Folder itself groups the documents by different document type. The checkmark indicates that there are related documents under the tab.

Approval Letter
When your protocol is approved you will receive an email notification. Should you require a copy of the approval letter for your protocol, open the Currently Approved version of the protocol and click on the Create PDF link in the side bar. The system will generate a PDF of the protocol as well as a copy of the related approval letter.

Post Approval Review (PAR)
The functionality for Post Approval Review will be rolled-out to users at a future date.

Designate
Principal Investigator Assistants
You may designate two types of PI Assistants; Staff PIAs and Student PIAs. Both types of PIAs have the same functionality but due to licencing restrictions Student PIAs will have their access to the system automatically terminated after 90 days. If the student is paid by the University, you may use the Designate PI Assistant function to provide extended system access.
PIAs may execute all MRHP related PI tasks with the exception of document creation and submission. This includes access to any previously submitted protocols. It is therefore very important that when delegating PIAs, the correct individuals are selected.

The following data points are displayed when selecting a staff member as a PIA:

- Name
- Department
- Email address

When selecting a student as a PIA, the student’s official U of T email address is displayed as a unique identifier.

The person you have designated will receive an email notification regarding the designation. It will take approximately 24 hours for the role to be activated.

**Instructors**

This role enables the user to submit a Course Template. Most users with this functionality will not see this role displayed separately as it has been incorporated into their PI role. However this role may be assigned manually where required, e.g. a Postdoctoral fellow who is teaching a course which requires a Course Template.

The Course Template employs the same user interface (protocol form), as the Investigator protocol submission, with the additional detail related to the course in Section 5 of the protocol application. When creating a new Course Template you will be provided with a list of your current courses as recorded in ROSI. If your course is not in the list a search box is provided.

Due to differences in the organizational structure employed in ROSI, you will need to manually enter the Division and Unit name of the Unit providing the course and to select the name of the Head of the Unit providing the course. This will route the protocol application to the appropriate individual for review and approval.
NB: Several departments and faculties have established their own Delegated Ethics Review Committees (DERCs) to review Course Template protocols. Do not submit a Course Template through MRHP if the protocol is minimal risk and your unit has a DERC. Course-based research reviewed through a DERC must be minimal risk. In exceptional circumstances, if a unit supports higher risk course-based research, protocols must be submitted through MRHP.

**Supervisors**

This role allows users to assign PI privileges to their students and postdocs who require protocols and to review their applications.

**Designate**

There are two ways in which a Supervisor may designate their students and postdocs; Course related designation and Non-Course related designation.

**Course-related protocols**

Select “Student PI – Course Related Projects” and follow the on screen instructions. You will see a list of your current courses as provided by ROSI. If you are missing a course, please contact the individual within your unit responsible for updating ROSI information. Follow the on-screen instructions to complete the set-up of students for the class. Students will receive an email notification informing them of their role.

**Non-Course Related**

Select “Student PI - Non-Course Related”. Search for the appropriate individual. When searching, in addition to the first and last name, you will see the email address which may be used as a unique identifier.
Supervisor Approval
Supervisors receive all protocols for review and sign-off prior to review by the relevant Unit Head. When your student/post-doc submits a protocol you will receive an email notification with a link to MRHP. You will find the protocol for your review in your MRHP Inbox with a “Review” task. Supervisors may not alter the protocol with the exception of Funding Information. Research accounts at the University are held in the name of the faculty member. If your student’s research is being supported by your funding this information should be added on the supervisor’s approval screen.
Supervised protocols list

Supervisors have a listing of all protocols submitted by their students and post docs. The list is accessible under the Supervisor link and functions in the same manner as the list of the PI’s protocols.

NB: Student legacy protocols, i.e. protocols by students/post docs submitted prior to MRHP, will not appear in this list as they were recorded under the faculty supervisor’s name. These protocols will appear on the faculty member’s list of protocols, (PI < My Human Research Protocols).